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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,695	02/11/2002	Lennart Olsson	213542000102	9893

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 08/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,695	OLSSON ET AL.	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20,21,30 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,21,30,31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Amendment of 5/27/05 has been entered. Claims 20-21 and 30-31 are pending. Claims 20-21 and 30-31 are under examination.

The amendment has overcome previously stated issues as follows:

The objection to the specification.

The rejection of claims 20 and 31 under 35 USC 112, 2nd paragraph.

The 102 rejection of claim 30 over Olsson et al (WO95/05189, US 5,639,548 or US 5,865,888). Examiner concurs that it is not proper to equate the internalization sequence derived from the receptor with the MHC sequence used to find the homologous internalization sequence of the receptor. While Olsson might have contemplated assays using oligopeptides that are of "substantially the same" sequence as the MHC class I derived oligopeptide, there is no teaching that theses "substantially the same" sequences would necessarily correspond to internalization sequences, because internalization sequences of receptors are a subset of many possible such "substantially the same" sequences. As claim 31 now depends from claim 30, there is no basis to reject claim 31 over prior art.

The following rejections of record are maintained or modified as follows:

Claims 30-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 30, step a) "bioactive peptide" is unclear because the activity of this peptide is not defined. Applicant may correct as in the amended version of step b).

Claims 20-21 and 30-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant was not in possession of the genus of "internalization sequences" as noted in the action of 2/25/05.

Applicant has urged that the rejection has been overcome by amendment of the claims. Claim 20 has not been amended in any manner that incorporates any feature not previously considered by the examiner, since its dependency from claim 13 was considered by the examiner. Claim 21 has not been amended in any manner that provides any structural feature of the internalization sequence. Claim 30 has been amended to define the sequence of the bioactive peptide, in terms of a SEQ ID NO; however, step a) does not adequately define what the "bioactivity" is. Claim 30 has not been amended to adequately define the "internalization sequence" of the receptor derived oligopeptide; the amendment merely provides a size limitation therefor; a size limitation, however, provides no description in terms of any structure or motif, such that an "internalization sequence" would be recognized as being such a sequence apart from other oligopeptides having a similar size limitation.

Applicant has urged that page 22 shows how to identify an "internalization sequence". Applicant is reminded that a process for identifying a compound or a composition does not define what the compound or composition is for the purposes of description. See Univ of Rochester... 69 USPQ2d 1886.

Applicant has urged that para. 3) of the previous rejection is not understood, because the only modifications contemplated by applicant involve inactivation of the internalization sequence. The examiner finds this argument unconvincing. It is noted that spec. page 8, lines 1-6 clearly contemplate that "modifications that do not substantially alter biological activity" are encompassed. Claim 20, part a) recites "altered by said modification", and it is to be noted that "altered" encompasses more than "inactivation".

Given the high degree of variability of alpha-1 domains of MHC class I antigens, and the uncertainty as to what the modifications result in, in terms of structure, the genus of "internalization sequences" remains not described.

Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Olsson et al (WO/95/05189).

Claim 21 is rejected under 35 U.S.C. 102(f) or (g) as being anticipated by Olsson et al (5,639,548 and 5,865,888).

Applicant has urged that the examiner's rejection has erred by "equating the natural sequence derived from the receptor and the MHC sequence used to find the natural sequence." This argument is only relevant to claim 30; as noted supra the examiner has withdrawn the rejection of claim 30.

Applicant has urged that at the time of the reference "a key reagent was not known" and that this is "particularly cogent in the case of claim 20". The examiner notes that claim 20 was not rejected and was, in fact, indicated as being allowable.

Applicant has urged that claim 21 cannot be anticipated because there was no knowledge of the internalization sequence at the time of the reference. Examiner notes that such knowledge of the internalization sequence would not have been necessary for anticipation, because the claim merely calls for use of the cell surface receptor, in other words the intact receptor, rather than an oligopeptide derived therefrom, having internalization activity. Olsson clearly teaches that "the screening assay may involve competition of the drug candidate with peptide for association with...receptor; see page 19, lines 10-12. Whether realized by the reference or not, the taught receptors inherently had an internalization sequence, within the intact receptor (instant disclosure provides the evidence of inherency). In the case where one conducts a competitive binding assay –e.g. with intact receptor on a solid phase, candidate drug (bioactive agent) and a labeled taught MHC class I oligopeptide, one would be conducting an assay in which the labeled MHC class I oligopeptide would bind with the receptor, at the latter's "internalization sequence" (again, examiner relies on instant disclosure for the teaching of inherency). Any competitive effect that the candidate drug might have against such binding would be due to binding of the drug to the intact receptor, at the latter's internalization sequence. In other words a competitive binding assay provides an indirect measure of the degree of binding of the candidate drug/bioactive agent to the cell surface receptor, at the latter's internalization sequence (e.g. note teachings of Olsson et al concerning the nature of competitive binding assays at page 21, first para. and page 23, first full para.). This is sufficient to anticipate claim 21.

Claims 20-21 and 30-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6,346,390. Although the conflicting claims are not identical, they are not patentably distinct from each other because of reasons set forth in the action of 2/25/05. No disclaimer has been provided.

Applicant's arguments filed 5/27/05 have been fully considered but they are not persuasive for the reasons stated above.

Applicant's amendment has necessitated the following new ground(s) of rejection.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 contains new matter in the preamble because the bioactive agent "of more than 100 and less than 2,500 daltons" is not limited to an organic compound, as disclosed at page 23, line 15. By merely limiting the molecular weight of the candidate agent, applicant has created a new subgenus of agents that was not originally described. For example, the claim would encompass the screening of polyphosphates, which are not organic.

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In

claim 30, steps a) and b), it is not clear where there is disclosure support for recitation of "at least a portion" of SEQ ID NO:1: in other words there is new matter. Also there is a description problem, due to the fact that in claim 30, parts b) the "bioactive peptide" can be modified by deletions from SEQ ID NO:1, such that a portion of SEQ ID NO: 1 can still "bind to said internalization sequence". Since said "internalization sequence" itself has not been described (as stated supra), any variants of SEQ ID NO:1 that bind to this "internalization sequence" cannot have been described.

Applicant's amendment prompted the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-

0849. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 7/28/05 DAS

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644